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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/171,740	04/20/1999	FRANCIS XAVIER IGNATIUS	10391/003001	8400

7590

02/12/2004

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EXAMINER

BENNETT, RACHEL M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/171,740	Applicant(s) IGNATIUS ET AL.	
	Examiner Rachel M. Bennett	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-21, 40 and 65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-21, 40 and 65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1, 4-21, 40, 65 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/22/03 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 4-21, 40, 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalaby et al. (WO 94/15587).

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Applicants claim a method of making microparticles of a sustained release ionic conjugate containing a free carboxyl group-containing biodegradable polymer and a free amino group-containing drug which are ionically bonded to each other, the method comprising: obtaining a first solution in which said conjugate is dissolved, wherein the solution comprises at least one part acetone, acetonitrile, ethyl acetate, tetrahydrofuran, glyme or any combination thereof; adding said first solution through an atomizing nozzle to a first liquid to form a first dispersion, wherein said first liquid is miscible with said first solution, and said conjugate is not soluble in said first liquid and precipitates out of said first dispersion; and isolating said conjugate from said first dispersion.

Shalaby et al. disclose peptide-polymer ionic conjugate microparticles wherein the polymer is a polyester that is the same as the instant invention. See pages 4-5 and 6-7, Tables 1-3, 6 and Example 11. The disclosed peptide is either LHRH or somatostatin. Example 11 of Shalaby teaches the instant methods. Ionic conjugates are formed by dissolving a biodegradable polymer in a liquid, while a peptide (drug) is dissolved in another liquid. These liquids are essentially mixed to form the peptide-polymer ionic conjugate and added to acetone. On pages 4-5 and 6-7, Shalaby discloses that tetrahydrofuran (THF) or acetonitrile, or mixtures thereof is substituted for or with acetone. The acetone/peptide-polymer solution is then injected into water or alcohol in small droplets. See page 27, lines 3-4. The polymer/peptide complex then separates immediately into small particles which are then subjected to reduced pressure to remove residual acetone and centrifuged. Shalaby is silent as to limitations of the instant claim 11, where the alcohol is maintained between 0 C to about -30 C or 0 C and -70 C. However, since the process of Shalaby is otherwise the same as the instant claims and results in the

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formation of microparticles, the temperature limitations of the instant claim 11 are not afforded patentable weight absent a demonstration of criticality thereto. Furthermore, it would be within the gambit of one skilled in the art to form the microparticles at a temperature that allowed for the quickest, most easily formed, or desirable microcapsules.

Response to Arguments

5. Applicant's arguments filed 12/22/03 have been fully considered but they are not persuasive.

Applicants argue that the Shalaby reference does not teach that the first solution is added to the first liquid in the form of small droplets through an atomizing nozzle. It is the position of the examiner that Shalaby teaches injecting a first solution as small droplets to a first liquid to form a first dispersion. While the reference teaches uses a teflon filter, it is known in the art that syringes equipped with teflon filters are used for injection of solutions via 0.2 μ teflon filters. Such filters can be fitted with needles for better control of the injection and would produce small droplets. Both the instant application and the prior art desire control over adding the first solution as small droplets to a first liquid to form a first dispersion. Therefore, the rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (571) 272-0589. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

rmb



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